Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The Effect of Ginger supplementation and high intensity Interval Training on metabolic status, serum irisin and anthropometric indices in obese men

Protocol summary

Study aim

Determining the effect of ginger supplement and high intensity inteval training on metabolic status, serum irisin and anthropometric indices in obese men

Design

Samples were selected using available methods and randomly assigned random blocks of 4 volumes to the study groups. A random sequence is generated using the STATA14 software. During the random assignment, individuals in the groups will be classified according to age and BMI variables.

Settings and conduct

In this study, samples from obese men aged 20 to 35 are selected by public call in different places. The participants will be those who are not already under any specialist diet program, etc. Therefore, people who are not currently willing to receive a diet are enrolled in the study. The company will be volunteers. At the beginning of the study, the objectives will be fully explained to the participants and written consent will be obtained. After explaining the conditions of the study, those who were willing to participate in the study, and also had criteria for entry, were selected and will be included in the study for 10 weeks. They will then be informed of the written consent form of the company and will be assured in order to preserve the information and to make the cooperation optional. Samples were selected using available methods and randomly assigned random blocks of 4 volumes to the study groups. A random sequence is generated using the STATA14 software. During the random assignment, individuals in the groups will be classified according to age and BMI variables

Participants/Inclusion and exclusion criteria

Inclusion criteria:Male gender Desire to cooperate and sign a informed consent form after full knowledge of the goals and method of carrying out the study Age group 20 to 35 years old BMI kg / m ^ 2 40-30 Exit criteria: Follow certain diets in the last 6 months Using drugs (glucose, statins, glucocorticoids ...) or other food supplements Participate in any regular sports activities smoking Food allergy People with diabetes, cardiovascular disease, respiratory disease, hyperthyroidism or hypothyroidism, kidney liver disease, digestive disease or other illnesses.

Intervention groups

Intervention group: Recipe daily 3 g ginger (three capsules of 1 g) Intervention group: Ginger plus to HIIT Exercise (daily g3 ginger is as three capsules of 1 gram and HIIT exercise for 10 weeks a week, 3 sessions and a total of 30 sessions) Intervention group: Practice HIIT plus to Placebo (3 g starch daily in the form of three capsules of 1 g and a HIIT exercise for 3 weeks each week and a total of 30 sessions per week) Control group: Placebo (3 g starch per day, 3 capsules per gram)

Main outcome variables

The results of this study can be helpful in providing appropriate strategies for controlling obesity and metabolic complications.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100408003664N20**
Registration date: **2018-03-20, 1396/12/29**
Registration timing: **prospective**

Last update: **2018-03-20, 1396/12/29**
Update count: **0**

Registration date

2018-03-20, 1396/12/29

Registrant information

Name

Maryam Rafraf

Name of organization / entity

Tabriz University Of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-04-04, 1397/01/15
Expected recruitment end date
2018-07-22, 1397/04/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Ginger supplementation and high intensity Interval Training on metabolic status, serum irisin and anthropometric indices in obese men

Public title
The Effect of Ginger supplementation and high intensity Interval Training on metabolic status, serum irisin and anthropometric indices in obese men
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Male gender Desire to cooperate and sign a informed consent form after full knowledge of the goals and method of carrying out the study Age group 20 to 35 years old BMI 30-40 kg/m2
Exclusion criteria:
Follow certain diets in the last 6 months use of drugs glucose lowering agent, statins, glucocorticoids ... or food supplements Participate in any regular sports activities Smoking Food allergies People with diabetes, cardiovascular disease, respiratory disease, hyperthyroidism or hypothyroidism, kidney liver disease, digestive disease or other illnesses
Age
From **20 years** old to **35 years** old
Gender
Male

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
Samples were selected using available methods and randomly assigned random blocks of 4 volumes to the study groups.A random sequence is generated using the STATA14 software.During the random assignment, individuals in the groups will be classified according to age and BMI variables.
Blinding (investigator's opinion)
Double blinded
Blinding description
Samples were selected using available methods and randomly assigned random blocks of 4 volumes to the study groups. A random sequence is generated using the STATA14 software. During the random assignment, individuals in the groups will be classified according to age and BMI variables
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tabriz University of Medical Science
Street address
Tabriz University of Medical Science, Attar Neishabouri Avenue, Golgasht street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5138663134
Approval date
2018-03-03, 1396/12/12
Ethics committee reference number
IR.TBZMED.REC.1396.1096

Health conditions studied

1

Description of health condition studied
Obesity
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description

Total Cholesterol
Timepoint
Before the intervention and 10 weeks after starting
Method of measurement
Enzymatic method

2

Description
Triglyceride
Timepoint
Before the intervention and 10 weeks after starting
Method of measurement
Enzymatic method

3

Description
HDL-C
Timepoint
Before the intervention and 10 weeks after starting
Method of measurement
Enzymatic method

4

Description
LDL-C
Timepoint
Before the intervention and 10 weeks after starting
Method of measurement
Formula

5

Description
Glucose
Timepoint
Before the intervention and 10 weeks after starting
Method of measurement
Enzymatic method

6

Description
Insulin
Timepoint
Before the intervention and 10 weeks after starting
Method of measurement
ELISA

7

Description
HOMA-IR
Timepoint
Before the intervention and 10 weeks after starting
Method of measurement
Formula

8

Description
Irisin
Timepoint
Before the intervention and 10 weeks after starting
Method of measurement
ELYSA

9

Description
Anthropometric Indicators
Timepoint
Before the intervention and 10 weeks after starting
Method of measurement
Metre

Secondary outcomes

1

Description
Diet
Timepoint
Before the intervention, 5 weeks after it and 10 weeks after its start
Method of measurement
3-day food record

2

Description
Physical activity
Timepoint
Before the intervention and 10 weeks after starting
Method of measurement
Before the intervention and 10 weeks after it begins

Intervention groups

1

Description
Intervention group: Recipe daily 3 g ginger (three capsules of 1 g)
Category
Treatment - Other

2

Description
Intervention group: Ginger plus to HIIT Exercise (daily g3 ginger is as three capsules of 1 gram and HIIT exercise for 10 weeks a week, 3 sessions and a total of 30 sessions)
Category
Treatment - Other

3

Description
Intervention group: Practice HIIT plus to Placebo (3 g starch daily in the form of three capsules of 1 g and a HIIT exercise for 3 weeks each week and a total of 30 sessions per week)

Category
Treatment - Other

4

Description
Control group: Placebo (3 g starch per day, 3 capsules per gram)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Student dormitories
Full name of responsible person
Mohammad bakhshi
Street address
Health and Nutrition School, Attare Neishaboori Avenue, Golgasht Street
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Tabriz
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5166614711
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Email
bakhshi.msh@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Nutritional Reseach Center of Tabriz University of Medical Sciences
Full name of responsible person
Alireza Ostadrahimi
Street address
Health and Nutrition School, Attare Neishaboori Avenue, Golgasht Street
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5166614711
Phone
+98 41 3336 3430
Email
nut-rc@tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Nutritional Reseach Center of Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mohammad bakhshi
Position
MS student in Nutrition
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Mohammad Bakhshi

Position

کارشناسی ارشد علوم تغذیه

Latest degree

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Other areas of specialty/work

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bakhshi.msh@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available